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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/088,078   | 07/22/2002  | John Alexander Edgar | 025217-0104         | 7566             |
| 22428  | 7590        | 10/01/2003           | EXAMINER            |                  |
| FOLEY AND LARDNER<br>SUITE 500<br>3000 K STREET NW<br>WASHINGTON, DC 20007 |             |                      | RUSSEL, JEFFREY E   |                  |
|  |             |                      | ART UNIT            | PAPER NUMBER     |
|  |             |                      | 1654                |                  |

DATE MAILED: 10/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/088,078

Applicant(s)

EDGAR, JOHN ALEXANDER

Examiner

Jeffrey E. Russel

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 22 July 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-6, 12, 13, 15 and 16 is/are allowed.
- 6) ☒ Claim(s) 9, 14 and 17-19 is/are rejected.
- 7) ☒ Claim(s) 7, 8, 10 and 11 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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1. Claims 9, 14, 17, and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 9 as amended in the preliminary amendment omitted the reference to the tripeptide and the indication that the di or tripeptide is optionally bound to the antibody. Accordingly, in the amended claim, the meaning of the word “tri” is unclear, as is the relationship of the monoclonal antibody and  $R^4$ . There is no antecedent basis in the claims for the phrase “said phomopsin or derivative thereof” at claim 14, lines 1-2. Note that independent claim 1 does not recite derivatives of phomopsins. At claim 17, line 2, the word “derivative” is indefinite because it is unclear what constitutes a “derivative” of phomopsin. It is not clear what degree of functional and/or structural similarity a compound must have with phomopsin in order for the compound to be considered a derivative of phomopsin. While the specification gives examples of phomopsin derivatives, e.g., antibody conjugates and salts, an example does not constitute a definition. Contrast the use of “derivative” in independent claim 17 with its use in dependent claim 3, where because of its dependency upon claim 1, the derivatives must still be phomopsins. Amended claim 19, now dependent upon claim 18, is unclear because claim 19 refers to the compound of formula I, whereas claim 18 is limited to compounds of formula Ia.

2. Claims 7 and 10 are objected to because of the following informalities: Claim 7 does not appear to end with a period (although this may be an effect of the image file wrapper system). At claim 10, line 6, a space should be inserted between “and” and “ $R^{12}$ ”. Appropriate correction is required.

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

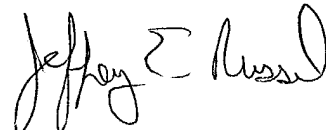
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 17-19 are rejected under 35 U.S.C. 102(b) as being anticipated by the Australian Patent 64916/90. The Australian Patent teaches compositions comprising optionally conjugated phomopsin and a carrier such as water. Phomopsin A is the main mycotoxin. See, e.g., page 1, line 33 - page 2, line 14, and Examples 3 and 6E. While the Australian Patent does not teach the use of these compositions to treat cancer, an intended use limitation does not impart patentability to composition claims where the composition is otherwise anticipated by the prior art.

5. Claims 1- 6, 12, 13, 15, and 16 are allowed. Claims 8 and 11 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claims 7 and 10 would be allowable if rewritten or amended to overcome the claim objections set forth in this Office action. Claims 9 and 14 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action. The prior art of record does not teach or suggest the use of phomopsins to treat cancer in patients. The Van Aswegen et al article is deemed to be the closest prior art of record. However, its in vitro studies are too preliminary to provide the reasonable expectation of success necessary to support prima facie obviousness.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (703) 308-3975. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Brenda Brumback can be reached at (703) 306-3220. The fax number for Technology Center 1600 for formal communications is (703) 872-9306; for informal communications such as proposed amendments, the fax number (703) 746-5175 can be used. The telephone number for the Technology Center 1600 receptionist is (703) 308-0196.



Jeffrey E. Russel

Primary Patent Examiner

Art Unit 1654

JRussel

September 29, 2003